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(54) **Surgical drape**

(57) This invention relates to surgical drapes and in particular provides a drape which comprises a thin, flexible, adhesive-coated plastics film and a protective, releasable layer applied to the adhesive coating, the drape having an aperture through at least the adhesive-coated film to permit, in use, access to a wound area, at least one first edge of the drape having a non-adhesive coat-

ed handling bar for separating the adhesive-coated film from the protective layer, and wherein the protective layer comprises a separate strip extending parallel to the first edge of the drape, and which protects the adhesive coating in the region of the aperture and carries at least one flap overlapping the adjacent portion of the protective layer, said flap constituting a handle for facilitating removal of said strip prior to use.

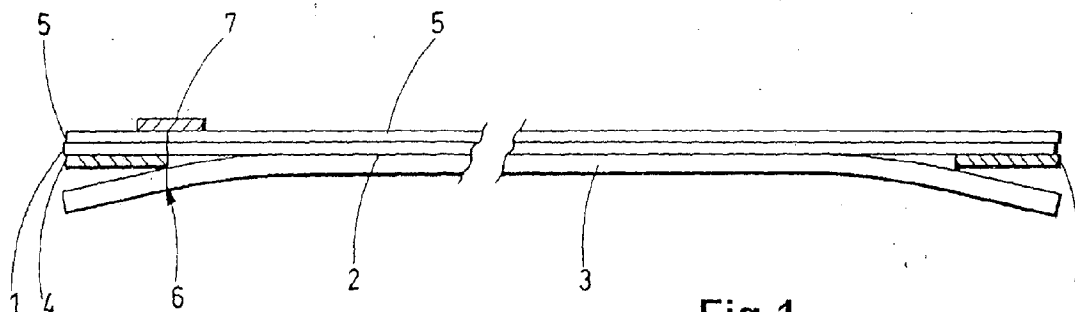


Fig.1

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Description

[0001] This invention relates to surgical drapes for wound treatment.

[0002] Surgical drapes are widely used in surgical operations for the purpose of reducing infection and facilitating the handling of skin around incisions. Normally, they are transparent or translucent. Typically, they consist of a flexible plastics film which is adhesive-coated and which is applied to the area of the operation, prior to making the incision. Surgical drapes are also used for attaching treatment devices to patients after an operation, such as catheters or drainage tubes.

[0003] A further, recently developed use is for connecting a suction tube to a wound for the purpose of stimulating healing of the wound. Such use is described in our earlier PCT Applications Nos. WO 96/05873 and WO 97/18007.

[0004] Various proposals have been made in the past to design the surgical drape so that handling of the sticky, flexible plastics film is facilitated. For example, US Patent No 5,437,622, describes a surgical drape which is a laminate of three materials. The first material comprising a transparent, thin plastics film which is adhesive-coated and this is protected with a layer of release-coated paper. The other face of the adhesive-coated film is strengthened with a reinforcing layer of a less flexible plastics film. Handling bars or strips are attached to the flexible plastics film at its lateral edges to facilitate handling of the flexible plastics film after stripping away the protective releasable layer.

[0005] Where it is desired to use a surgical drape primarily to attach a device such as a catheter to a wound area after an operation or for long term treatment, it is inconvenient for the surgeon or nurse to have to adapt a standard surgical drape for this purpose. It would be more convenient to have a surgical drape which was suitable without adaptation to accommodate the treatment device.

[0006] One aspect of the present invention is directed to a solution to this problem.

[0007] According to the present invention there is provided a surgical drape which comprises a thin, flexible, adhesive-coated plastics film and a protective, releasable layer applied to the adhesive coating, the drape having an aperture through at least the adhesive-coated film to permit, in use, access to a wound area, at least one first edge of the drape having a non-adhesive coated handling bar for separating the adhesive-coated film from the protective layer, and wherein the protective layer comprises a separate strip extending parallel to the first edge of the drape, and which protects the adhesive coating in the region of the aperture and carries at least one flap overlapping the adjacent portion of the protective layer, said flap constituting a handle for facilitating removal of said strip prior to use.

[0008] In practice, surgical drapes may be manufactured by laminating an adhesive-coated flexible film,

such as a polyurethane film, to a protective releasable layer, such as a siliconised paper. A strengthening layer of thicker plastics material, e.g. a polyolefin such as polyethylene, may be applied to the non-adhesive coated face of the flexible film, so that a three-layer laminate is produced. These laminates are produced in substantial width and may be slit longitudinally to the desired width and then laterally to form drapes of the desired size.

[0009] After slitting to a desired width, handling bars are normally applied to the adhesive-coated layers at one or both lateral edges to facilitate separation of the film from the protective, releasable layer. While an aperture could be cut at the desired position through the layers to accommodate a catheter or a device such as those described in our above-mentioned applications, it is difficult to handle the highly pliable and adhesive film after the releasable layer has been stripped off.

[0010] Although the strengthening layer does somewhat improve the handling characteristics, this is not a complete answer to the problem. However, the handling characteristics are substantially improved by the protective layer which is in at least two portions, one of which is in the form of a strip, e.g. one extending parallel to the lateral edges of the drape, and covering the peripheral area around the aperture through the drape. By providing a flap on this portion of the releasable layer, it can be stripped off initially so that the drape is first positioned around the device which is to pass through the aperture, and then the remaining part of the protective releasable layer is stripped off to adhere the drape to the patient's skin around the area to be treated.

[0011] In a preferred form of the invention in which negative pressure therapy is applied to a wound area, the surgical drape described above is combined with a suction head having a connector piece which is adapted to be connected to a suction tube. Thus, in this embodiment, the suction head can be adhered to the patient's skin in the area of the wound after removing the strip of protective releasable layer, and then the remaining part of the drape is affixed to the patient's skin. In this way, the suction head is held firmly in place and, at the same time, seals the suction head to the wound area and prevents leakage of air from atmosphere into the wound area.

[0012] The drape of the invention is preferably used in combination with a suction head having a design which facilitates the suction of fluid from a wound area that is claimed in parent application no. 98941623.5. Application No. 98941623.5 relates to a suction head for applying suction to a wound area which comprises a generally planar flange portion and a tubular connector piece on a first face, for connecting a suction tube to a aperture through the flange portion to the other face, said other face having projections defining slow channels facilitating flow of fluid towards said aperture.

[0013] Preferably, the suction head described above is combined with the surgical drape of the present invention, with the tubular connector piece extends

through the aperture in the plastics film with the adhesive coated adhered to said first face of the flange portion.

[0014] Preferably, the suction head is used in conjunction with an open-celled foam pad so that one surface of the foam pad is placed in contact with a wound area and the suction head applied to the other surface of the foam pad. In the case of deep wounds the foam may be shaped and placed so that it is packed into the wound cavity as described in our above cited PCT applications. According to another technique, which is particularly applicable to superficial wounds, the foam pad may be a relatively thin pad which is placed over the wound. The suction head is placed in contact with the open face of the foam pad and the drape applied over the suction head to fix the assembly to the patient's skin.

[0015] Various types of open celled foams can be used as described in our above cited PCT applications. The foam may be a polyurethane form but polyvinyl acetate (pva) foams are preferred, especially when used as a pad which is placed over the wound. These are to some extent hydrophilic, which seems to exhibit beneficial comfort properties when applied to the skin. Wound healing is stimulated by maintenance of moist conditions in the wound area, and this is facilitated by using a hydrophilic foam.

[0016] Further features and advantages of the present invention will be apparent from the following description and accompanying drawings, of non-limiting examples in accordance with the invention.

[0017] Referring to the accompanying drawings:-

Figure 1 represents a conventional design of surgical drape;

Figure 2 represents a variation in the design of the handling bars at one end of the drape shown in Figure 1;

Figure 3 is a view similar to Figure 1 of a surgical drape in accordance with the invention;

Figure 4 is a plan view of the surgical drape shown in Figure 3,

Figure 5 is a plan view from beneath of a suction head in accordance with the invention, and

Figure 6 is a side elevation of the suction head shown in Figure 5;

Figure 7 is a view similar to Figure 6 but shows the suction head secured to a skin surface with the drape and with a foam pad located between the head and the skin surface;

Figure 8 is a perspective view of the drape with a central strip portion of the protective sheet in the course of being removed, and

Figures 9(a)~9(c) illustrate the steps of affixing the dressing assembly to a wound area on a patient's leg and attachment to a negative pressure assembly.

[0018] Referring to Figures 1 and 2 of the accompa-

nying drawings, a conventional laminate for use as a surgical drape comprises a thin, flexible, transparent plastics film 1 which is adhesive-coated on one face 2, normally with a high-tack pressure-sensitive adhesive, and is protected with a releasable layer 3. The thin plastics film is conveniently of polyurethane because it transmits moisture. Layer 3 is normally considerably thicker than film 1 and is coated on the surface adjacent to the adhesive with a releasable material such as a silicone to facilitate stripping away from the adhesive-coated film.

[0019] In order to facilitate removal of the adhesive-coated film prior to use of the device, handling bars 4 are bonded at each end to the adhesive-coated film 1. Thus, by holding one of the bars 4, the protective layer 3 can be stripped off and the adhesive face applied to the skin of the patient. To facilitate handling of the thin, flexible film 1, a strengthening plastics film 5 is frequently applied to the free face of the plastics film 1. This is generally also transparent or translucent. Film 5 is preferably not bonded with adhesive to film 1, but may remain in contact by reason of electrostatic forces or because of close contact between the two conforming surfaces of film 1 and film 5.

[0020] Usually, the surgeon or nurse will wish to strip off the protective layer 5 after the film 1 has been correctly placed on the patient's skin, and this can be facilitated by making partial cuts 6 through the films 1 and 5, so that as the handling bar 4 is drawn upwards from the patient's skin, the adhesive film 1 remains adhered to the patient, while the partial cuts 6 causes separation of the flexible film from the strengthening film 5. Strengthening bars 7 may be provided to hold the lateral edges of the strengthening film 5 and film 1 together with their main parts.

[0021] An alternative arrangement is shown in Figure 2, in which the strengthening film 5 is provided with a separate overlapping handling bar 14, to facilitate its removal from the flexible film 1.

[0022] Further details of the make-up and manufacture of surgical drapes are given in US Patent No. 5,437,622 and European Patent Application No. 0161865 and the prior art referred to therein.

[0023] Referring to Figures 3 and 4, the surgical drape of this invention composes a protective outer film 20, laminated to a thin, flexible film 21. The flexible film 21 includes an adhesive-coated layer which is protected with a release-coated sheet material 24. Lateral edges of the flexible film 21 are provided with handling bars 23. Thus far, the design is essentially the same as that shown in Figures 1 and 2.

[0024] The drape of the present invention differs from the drape shown in Figures 1 and 2 in that an aperture 25 is cut through the strengthening layer 20 and through the flexible layer 21. The other difference compared with the prior art drapes is that the protective releasable layer is formed in at least two sections.

[0025] In the embodiments shown in Figures 3 and 4,

the central portion of the releasable layer comprises a strip 26, having flaps 27 which overlap the remaining outboard portions of the releasable layer. The purpose of this is to enable the central strip 26 to be removed first, without disturbing the remaining portions of the releasable layer. The drape can then be fitted around the wound area and, if desired, a suction device or other treatment device passed through the aperture 25 and secured to the patient's skin with the peripheral areas of exposed adhesive-coated film.

[0026] An example of a device for applying suction to the wound area is illustrated in Figures 5, 6 and 7.

[0027] Referring to these Figures, the suction head comprises a flange portion 30 having a tapered edge 31, and a profile which may be of any desired shape but is generally rounded at its edges. On the face of the flange 30 intended for contact with the patient's skin or a foam pad are formed a series of projections 32 which are distributed over the surface of the flange apart from the peripheral edge portion 31. The purpose of these projections is to provide fluid channels 33 facilitating the flow of fluids from any point of the flange to a central point 34, from which it is intended to apply suction. The suction head includes a connector 35, located above the aperture 34, having a tubular end 36 adapted for receiving and connecting a catheter. The tubular end may have an outwardly tapered portion to facilitate feeding a catheter into the connector. The upper surface 37 of the suction head has a substantially smooth surface.

[0028] In use, the connector portion 35 is sized so that it extends through the aperture 25 in the surgical drape shown in Figures 3 and 4, with the adhesive surface around the aperture bonded to the smooth surface 37 of the flange 30. The suction head may be packaged in this condition with the surgical drape so that in use, the strip 26 is removed by pulling on the handles 27 thus exposing the adhesive surface in the vicinity of and surrounding the suction head. The suction head can then be fixed in the desired position on the patient's wound and then the remaining portion of the protective film removed to fix the drape to the patient. The flange 30 of the suction head may be somewhat oval as shown in Figure 5, and have dimensions as indicated in this Figure, i.e. a longer dimension of about 95mm and a short dimension of about 70mm. Alternatively, the flange may be circular and be smaller in plan view. For example, the diameter of a circular suction head may be from about 30 to 50mm in diameter, e.g. about 40mm. It has been found that the suction head flange should not overlap the area of the wound. Thus, in the case of smaller wounds a smaller suction head is indicated.

[0029] Figure 7 shows the suction head attached to a wound area 71 of a patient 70. The suction head is pressed into firm contact with a flexible, open-celled foam 73, which is itself pressed into contact with the wound area 71. The suction head and foam pad are pressed into contact with the wound area by a surgical drape 20 having an adhesive surface 74. The adhesive

surface is bonded to the patient's skin outside the periphery of the foam pad and suction head. It is also bonded to upper surface 37 of the suction head. An aperture is formed in the drape to permit the connector portion 35 to extend upwardly through the drape. In order to avert the danger of incorrect catheter tubes being fitted to the connector 35, the latter may have a customised cross-section or internal projection such as a rib or key which co-operates with a corresponding slot or key way in the catheter. Alternatively, the catheter may be moulded with a projection or longitudinal rib which co-operates with a corresponding slot or key way in the aperture of the connector 35.

[0030] The foam pad may be packaged in a plastic pouch, sterilised by gamma irradiation and supplied in the same box or in other packing units as the suction head and drape.

[0031] Figures 8 and 9(a)~(b) illustrate the way in which the drape/suction head combination is fitted to a wound on a patient's skin. In Figure 8, a backing sheet 101 having a release coated surface is removed in the first step from the adhesive face 102 of the drape to expose the face of the connector 30. A pad 103 of foam is positioned over the wound area and the drape placed over the foam pad, the drape being adhered to the skin above and below the pad (Figure 9a). The lateral protective strips 104 and 105 are removed in turn from the drape and the assembly adhered to the skin (Figures 9(b) and 9(c)). Finally, the spout 36 is connected to a tube 106 which is then connected to a source of suction, e.g. a pump as described in our above PCT application, in order to apply negative pressure to the wound. The suction head and drape assembly is shown in Figure 8, with the smooth surface 37 adhered to the drape, is conveniently packaged in an easily openable plastic bag or pouch, and sterilised for immediate use.

Claims

1. A surgical drape which comprises a thin, flexible, adhesive-coated plastics film (21) and a protective, releasable layer (24) applied to the adhesive coating, the drape having an aperture (25) through at least the adhesive-coated film to permit, in use, access to a wound area, at least one first edge of the drape having a non-adhesive coated handling bar (23) for separating the adhesive-coated film from the protective layer, and wherein the protective layer comprises a separate strip extending parallel to the first edge of the drape, and which protects the adhesive coating in the region of the aperture (25) and carries at least one flap (27) overlapping the adjacent portion of the protective layer, said flap constituting a handle for facilitating removal of said strip prior to use.
2. A surgical drape according to claim 1 having a

strengthening layer (20) applied to the face opposite to the adhesive coating.

3. A surgical drape according to claim 2, said strengthening layer being a plastics film which is thicker or less flexible than said adhesive-coated film. 5
4. A surgical drape according to claim 2 or claim 3 wherein said aperture goes through at least the strengthening film and adhesive coated film. 10

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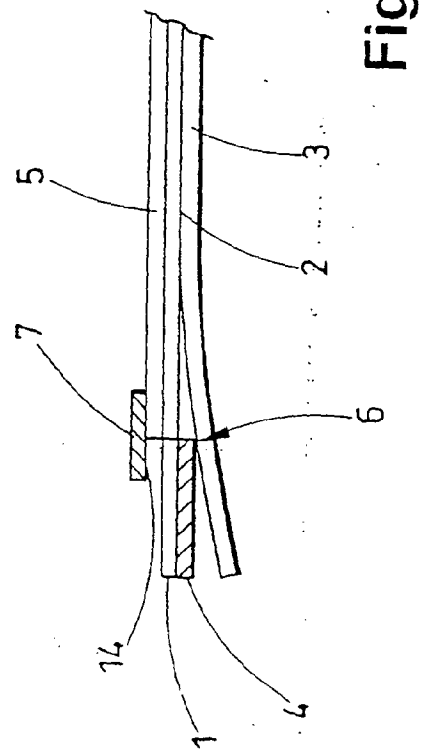
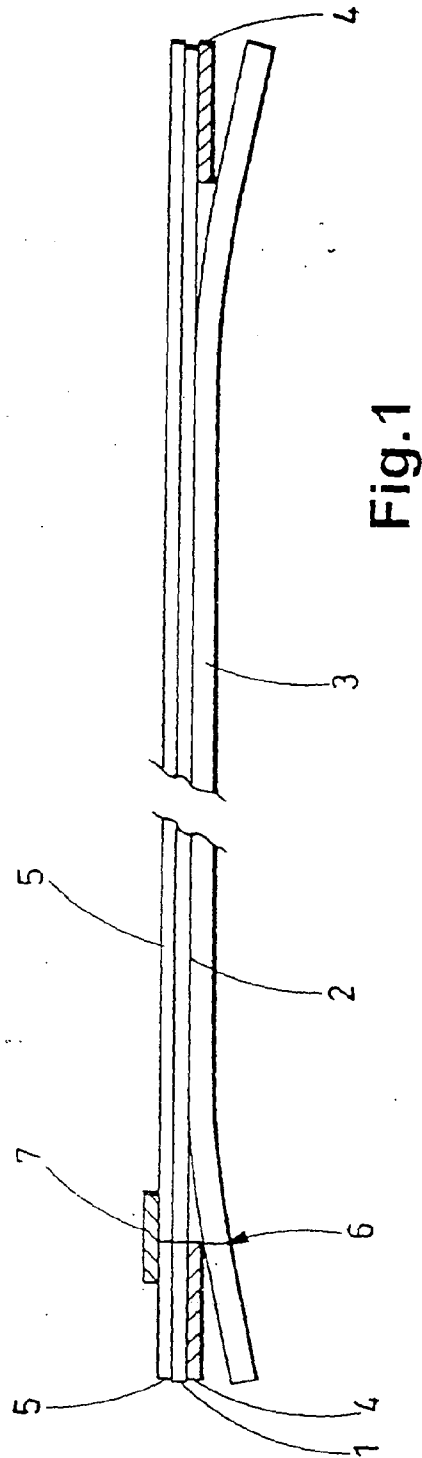
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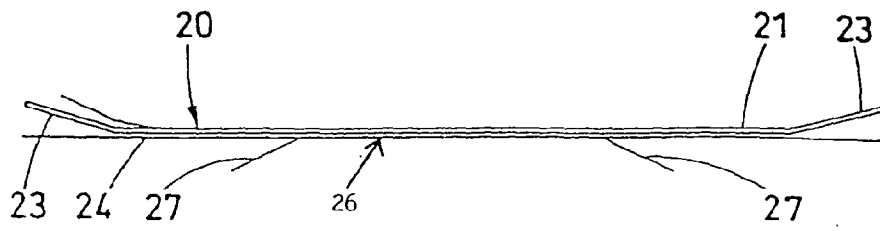


Fig. 3

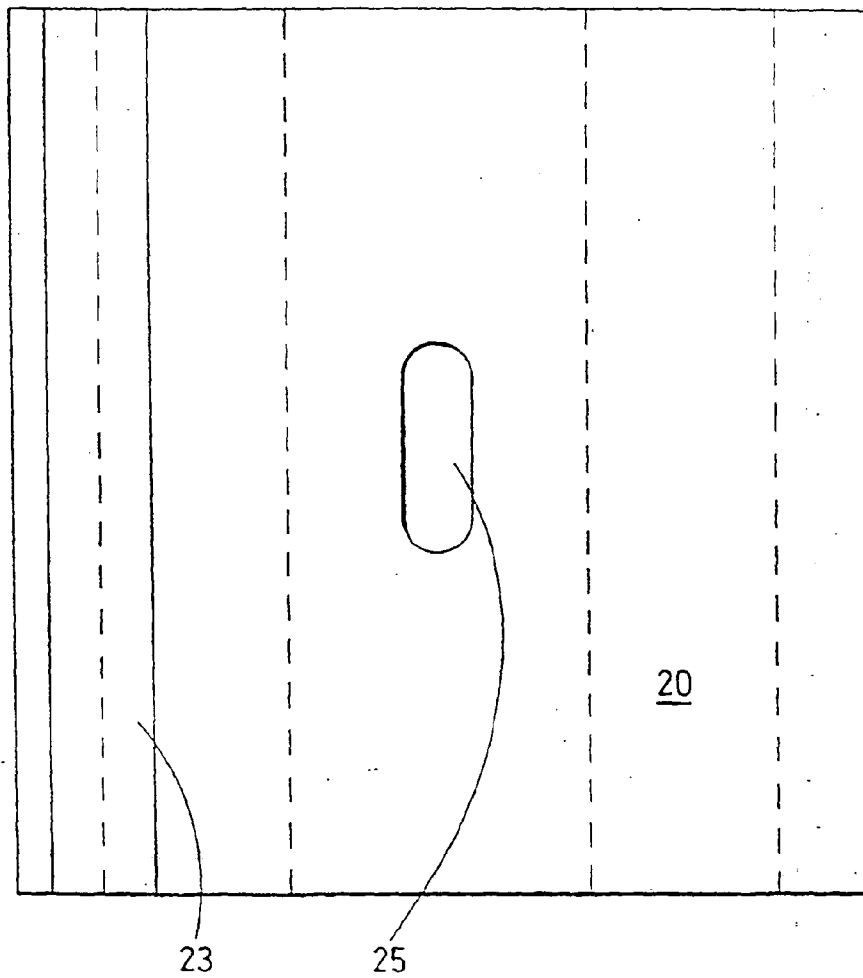


Fig. 4

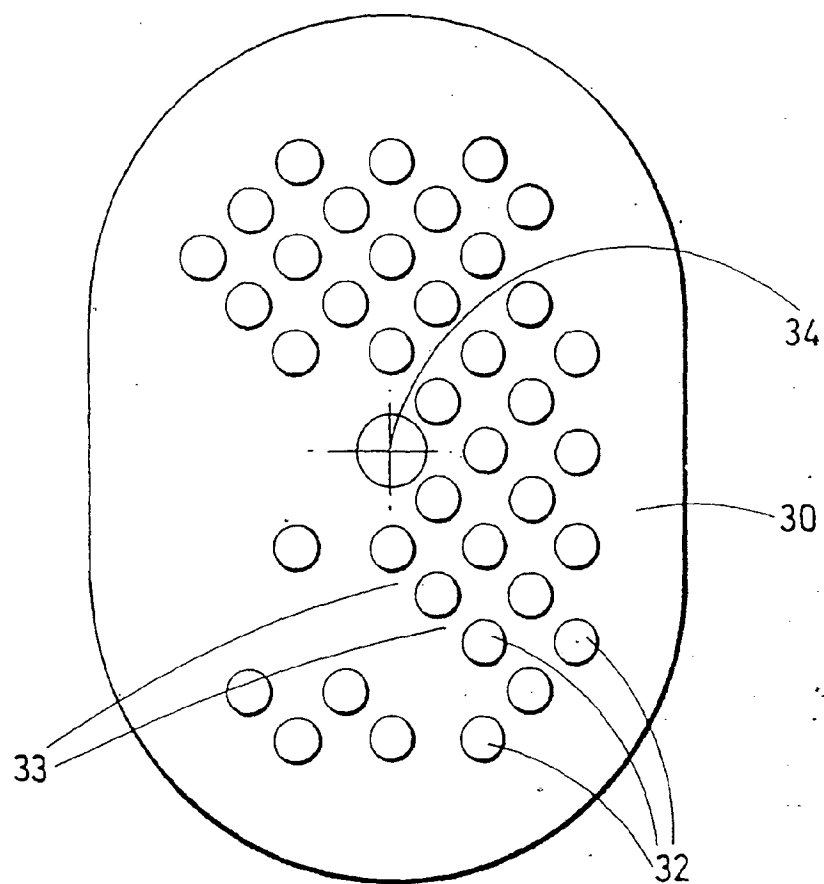


Fig. 5

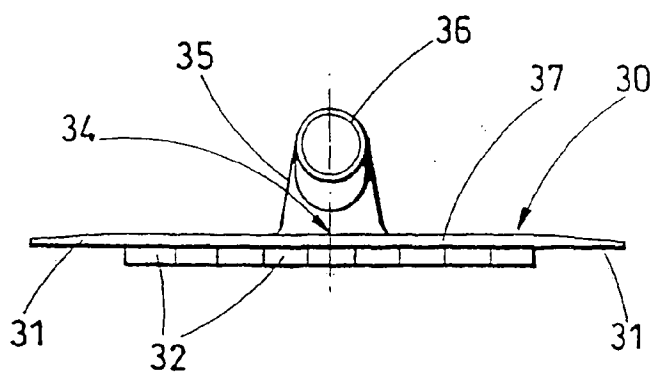
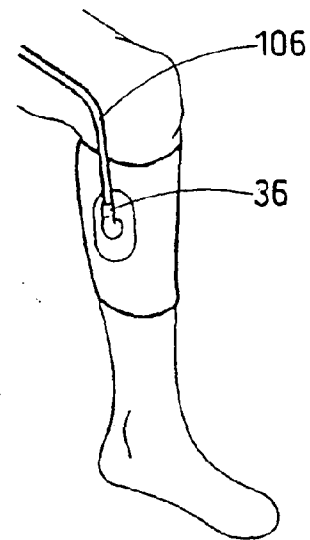
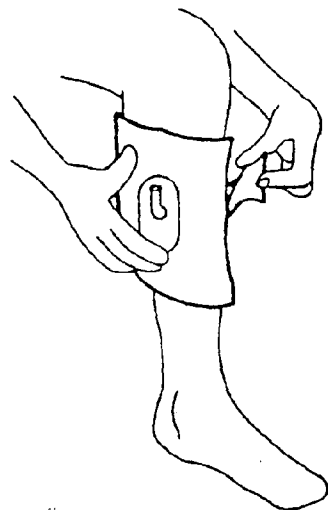
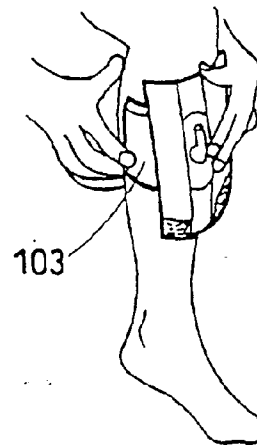
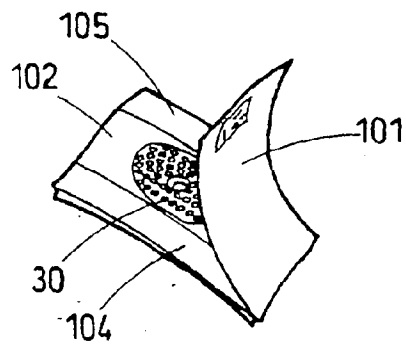
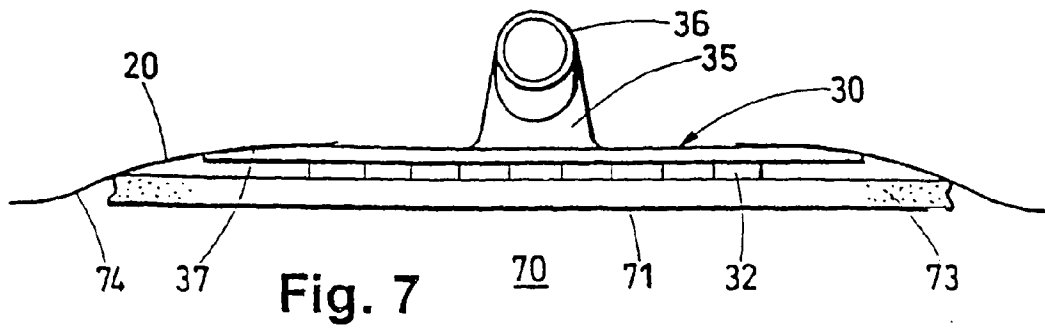


Fig. 6





European Patent
Office

EUROPEAN SEARCH REPORT

Application Number
EP 04 00 9482

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.7)
D,Y	US 5 437 622 A (CARION) 1 August 1995 (1995-08-01) * abstract; figure 1 * * column 3, lines 20-27 * * column 3, line 50 - column 4, line 2 * -----	1-6	A61B19/08 A61B19/10 A61F13/02
Y	EP 0 117 632 A (JOHNSON & JOHNSON PRODUCTS INC.) 5 September 1984 (1984-09-05) * abstract; figure 1 * * page 2, lines 8-10 * -----	1-6	
A	US 3 667 458 A (KREBS) 6 June 1972 (1972-06-06) * figures * -----	1	
D,A	WO 97/18007 A (KCI MEDICAL LIMITED) 22 May 1997 (1997-05-22) * page 8, line 5 - page 9, line 9; figures 6a,6c,7a,7b * -----	1	
A	US 5 636 643 A (ARGENTA ET AL.) 10 June 1997 (1997-06-10) * abstract * -----		TECHNICAL FIELDS SEARCHED (Int.Cl.7) A61B A61F
The present search report has been drawn up for all claims			
Place of search The Hague		Date of completion of the search 2 June 2004	Examiner Giménez Burgos, R
<p>CATEGORY OF CITED DOCUMENTS</p> <p>X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document</p> <p>T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document</p>			

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**ANNEX TO THE EUROPEAN SEARCH REPORT
ON EUROPEAN PATENT APPLICATION NO.**

EP 04 00 9482

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02-06-2004

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 5437622	A	01-08-1995	FR 2690617 A1	05-11-1993
			AT 144895 T	15-11-1996
			CA 2095073 A1	30-10-1993
			DE 69305779 D1	12-12-1996
			DE 69305779 T2	15-05-1997
			EP 0568401 A1	03-11-1993

EP 0117632	A	05-09-1984	AT 45501 T	15-09-1989
			AU 559680 B2	19-03-1987
			AU 2383284 A	02-08-1984
			BR 8400330 A	28-08-1984
			CA 1216203 A1	06-01-1987
			DE 3479401 D1	21-09-1989
			DK 35484 A	28-07-1984
			EP 0117632 A2	05-09-1984
			ES 284726 U	16-07-1985
			FI 840326 A	28-07-1984
			GR 81743 A1	12-12-1984
			HK 12390 A	23-02-1990
			IE 55980 B1	13-03-1991
			JP 59141943 A	14-08-1984
			MX 161286 A	29-08-1990
			NO 840309 A	30-07-1984
			NZ 206837 A	08-08-1986
			SG 1890 G	06-07-1990
			US 4614183 A	30-09-1986
			ZA 8400612 A	25-09-1985

US 3667458	A	06-06-1972	NONE	

WO 9718007	A	22-05-1997	AT 246945 T	15-08-2003
			AT 203174 T	15-08-2001
			CA 2237606 A1	22-05-1997
			DE 19681649 T0	03-12-1998
			DE 29623482 U1	23-07-1998
			DE 69613997 D1	23-08-2001
			DE 69613997 T2	31-10-2001
			DE 69629507 D1	18-09-2003
			DK 1088569 T3	08-12-2003
			DK 865304 T3	24-09-2001
			EP 1088569 A2	04-04-2001
			EP 0865304 A1	23-09-1998
			ES 2204800 T3	01-05-2004
			ES 2159050 T3	16-09-2001
			GB 2344531 A ,B	14-06-2000
			WO 9718007 A1	22-05-1997

EPO FORM P0456

For more details about this annex : see Official Journal of the European Patent Office, No. 12/82

**ANNEX TO THE EUROPEAN SEARCH REPORT
ON EUROPEAN PATENT APPLICATION NO.**

EP 04 00 9482

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02-06-2004

Patent document cited in search report	Publication date	Patent family member(s)	Publication date	
WO 9718007	A	GB 2307180 A ,B	21-05-1997	
		GB 2336546 A ,B	27-10-1999	
		GR 3036872 T3	31-01-2002	
		HK 1029536 A1	14-12-2001	
		HK 1012589 A1	02-03-2001	
		JP 2000500992 T	02-02-2000	
		PT 1088569 T	31-12-2003	
		PT 865304 T	30-01-2002	
		US 6142982 A	07-11-2000	

US 5636643	A	10-06-1997	US 5645081 A	08-07-1997
			AT 196235 T	15-09-2000
			AU 696031 B2	27-08-1998
			AU 6360894 A	26-09-1994
			CA 2157772 A1	15-09-1994
			DE 69425881 D1	19-10-2000
			DE 69425881 T2	22-03-2001
			DK 688189 T3	27-12-2000
			EP 0688189 A1	27-12-1995
			ES 2151925 T3	16-01-2001
			GR 3034817 T3	28-02-2001
			JP 9503923 T	22-04-1997
			PT 688189 T	28-02-2001
			WO 9420041 A1	15-09-1994
			US 2001029956 A1	18-10-2001
			AT 164055 T	15-04-1998
			AU 674837 B2	16-01-1997
			AU 3130393 A	15-06-1993
			CA 2121688 A1	27-05-1993
			DE 9219136 U1	18-06-1998
			DE 69224847 D1	23-04-1998
			DE 69224847 T2	20-08-1998
			DK 620720 T3	28-09-1998
			EP 0620720 A1	26-10-1994
			ES 2114956 T3	16-06-1998
			JP 7501958 T	02-03-1995
			WO 9309727 A1	27-05-1993

EPO FORM P0459

For more details about this annex : see Official Journal of the European Patent Office, No. 12/82